

REMARKS

Applicant has considered the Office Action of March 18, 2005. Claims 1 and 2 have been amended. New claim 18 has been added. Claims 1-15 and 18 are pending. Reconsideration of this application is respectfully requested.

I. The claims are not anticipated by Yallampali.

Claims 1-10 were rejected under 35 U.S.C. § 102(b) as anticipated by Yallampali. Applicants traverse the rejection.

Claims 1 and 2 have been amended to recite that adrenomedullin is administered without CGRP. Yallampali discloses the use of CGRP or CGRP/adrenomedullin and largely describes the utility of CGRP. He describes adrenomedullin as comparable to CGRP or an analog thereof, but does not disclose that adrenomedullin itself is effective to inhibit abnormal myometrial contraction caused by inflammatory mediators. He also discloses no experimental data showing the effect of adrenomedullin on abnormal myometrial contraction.

Yallampali does not teach the effect of administering adrenomedullin without CGRP. As indicated in prior responses, CGRP and adrenomedullin are also qualitatively different. Therefore, Applicant submits that the novel usage of adrenomedullin alone is not inherently disclosed by Yallampali. Withdrawal of the 102(b) rejection based on Yallampali is requested.

II. The claims are not rendered obvious by Yallampali.

Claims 1-15 were rejected under 35 U.S.C. § 103(a) as obvious over either Yallampali or Yallampali in view of Kitamura. Applicants traverse the rejections.

Claims 1 and 2 have been amended to recite that adrenomedullin is administered without CGRP. Yallampali does not provide an enabling disclosure for the use of adrenomedullin alone to inhibit abnormal myometrial contraction. Kitamura makes no reference to the use of adrenomedullin to inhibit myometrial contraction. Therefore, Yallampali and Kitamura, alone or in combination, do not teach or suggest the use of adrenomedullin as in the claimed methods. Applicant requests withdrawal of the 103(a) rejections based on Yallampali and Kitamura.

III. The claims are definite.

Claims 7-10 were rejected under 35 U.S.C. § 112, ¶ 2, as indefinite. The Examiner asserted the definition of adrenomedullin recited in the claims is inconsistent with what is conventionally known in the art. Applicant traverses the rejections.

In the paragraph beginning at page 10, line 23, of the specification (which begins with “AM used in the present invention...”), Applicant has defined the term “adrenomedullin”. While it may be defined differently from that which is conventionally known in the art, this is because Applicant uses the term to also include some analogs mentioned by the Examiner. Applicant may be his own lexicographer and in this case, uses one term, “adrenomedullin”, to convey multiple meanings. The definition provided in the specification controls the interpretation of the claims. MPEP § 2111.01(III); *Phillips v. AWH*, (Fed. Cir. July 12, 2005) (*en banc*) (“... the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.”). Applicants also note that here, the term is defined and used in a manner such that one skilled in the art would understand what subject matter is being claimed. The claims are therefore definite. Applicant requests withdrawal of the rejection based on § 112, ¶ 2.

IV. The claims are not anticipated by Samuelson.

Claims 1 and 7-10 were rejected under 35 U.S.C. 102(b) as anticipated by Samuelson. The Examiner asserted that CGRP reads on the claimed invention because CGRP is a deletion analog of adrenomedullin and since the claims allow for several amino acid deletions, it meets the limitations of those claims. Applicant traverses the rejections.

The CGRP peptide of Samuelson does not read on the subject matter of the claims. In particular, the claims intend to capture only those analogs which may match the claimed amino acid sequences after specific amino acid substitutions, not any amino acid substitution. Those specific amino acid substitutions are given in the paragraph beginning at page 10, line 30, of the specification (which begins with “Amino acid conservative substitution...”). The amino acid sequence of CGRP contains some amino acids which cannot be substituted for to obtain a claimed amino sequence. Figure 2 of Kitamura gives the amino acid sequences for both adrenomedullin and

CGRP. The amino acid sequence for residues 13-52 are reproduced below in the following lines. Substitutions not allowed by the current claims are in bold type:

Adrenomedullin: FGCR**RF**GTCT**TV**QKLA**HQ**I**YQ**FTDKDKDN**VAPRSKI**SPQGY

CGRP: ACDTATC**V**THRLAG**L**LS**RS**GG**V**V**K**NN**F**VP**T**NVGS**K**A-F

As can be seen, 23 amino acids cannot be substituted. Therefore, CGRP is a claimed analog and does not meet the claim limitations. Applicant requests withdrawal of the 102(b) rejections based on Samuelson.

CONCLUSION

In view of the above amendments and arguments, it is respectfully submitted that pending claims 1-15 and 18 are now in condition for allowance. Hence, withdrawal of the rejections and issuance of a Notice of Allowance is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is hereby authorized to contact Richard M. Klein at the telephone number listed below.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP



July 18, 2005

Date

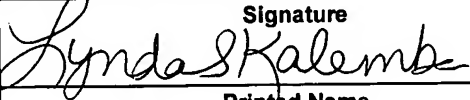
Richard M. Klein
Reg. No. 33,000
1100 Superior Avenue
7th Floor
Cleveland, Ohio 44114-2579
(216) 861-5582

Certificate of Mailing

Under 37 C.F.R. § 1.8, I certify that this Amendment is being

- ☒ deposited with the United States Postal Service as First Class mail, addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.
- ☐ transmitted via facsimile in accordance with 37 C.F.R. § 1.8 on the date indicated below.
- ☐ deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated below and is addressed to: MAIL STOP AMENDMENT, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date
July 18, 2005

Signature 
Printed Name Lynda S. Kalemba